



**PROLOTHERAPY FOR TREATMENT
OF JOINT AND LIGAMENTOUS CONDITIONS
HS-073**



Harmony Behavioral Health, Inc.

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**Prolotherapy for Treatment
of Joint and Ligamentous
Conditions**

Policy Number: HS-073

Original Effective Date: 12/18/2008

**Revised Date(s): 12/22/2009;
12/28/2010; 12/1/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Prolotherapy is proposed to stimulate the production of new ligament tissue by causing a controlled injury to a specific target area with the ultimate goal of strengthening the structure. This is usually achieved by injecting the ligament with any one of several different chemicals, usually referred to as proliferatives or sclerosing agents. Some of the proliferative agents used include zinc sulfate, psyllium seed oil, hypertonic glucose, and phenol or carbolic acid, which may be mixed with glycerol. Proliferatives act as inflammatory agents that cause minor injury to the ligament and, in theory, initiate the first step in the wound healing process, leading to new collagen formation. Prolotherapy may involve a single injection or a series of injections, often diluted with local anesthetic agents such as Lidocaine or Marcaine. Sarapin® is another agent thought to have anesthetic properties. It is a derivative of the Sarraceniaceae plant and has been used in combination with sclerosing agents in prolotherapy.

Prolotherapy methods are based largely on anecdotal evidence and physician preference; therefore, protocols vary greatly between physicians. In addition, treatment methods are often tailored to the individual needs of the patient. Prior to injection, the physician attempts to identify pain trigger points during a physical examination. In some cases, the patient is sedated with oral or intravenous medication prior to injections. The sclerosant is injected next to the painful site at the interface between the bone and tendon, ligament, or fascia. Injection of a local anesthetic may precede the injection of the sclerosant. For patients with lower back pain, the physician generally administers 0.5 to 2.0 mL of sclerosant into each site using a 2.5-inch, 20-gauge spinal needle. Target sites include the iliolumbar ligaments, posterior sacroiliac ligaments, interspinous ligaments, supraspinous ligaments, and posterior intervertebral facet capsules.

Proposed Mechanism of Action by Sclerosant Type

Chemical irritants: Chemical sclerosants have phenolic hydroxyl groups that are readily oxidized to produce quinone-like compounds. The phenolic hydroxyl groups, or their quinoid oxidation products, attach to the surfaces of the cells at the injection site. Although the exact mechanisms are not completely understood, it is postulated that chemical irritants cause damage to the cells directly or render the cells antigenic. In either case, granulocytes and macrophages are attracted to the injection site, causing inflammation and the initiation of the healing process.

Osmotic shock agents: Osmotic sclerosants, concentrated solutions of simple water-soluble compounds, include concentrated glucose, glycerine, or zinc sulfate. Osmotics act by dehydrating cells at the injection site, causing localized tissue trauma. Dead or morbid cells at the injection site release cellular fragments that attract granulocytes and macrophages. Thus, the local tissue damage promotes the influx of inflammatory cells and initiates the wound healing cascade.

Chemotactic agents: Morrhuate sodium, a fatty acid derivative of cod liver oil, contains the biosynthetic precursor to certain chemotactic agents that attract inflammatory cells. Prolotherapy advocates hypothesize that the proliferative action of sodium morrhuate may be due to its arachidonic acid component being directly converted into prostaglandins and related mediators of inflammation (Hayes, 2008).

There is a lack of scientific data demonstrating the effectiveness of prolotherapy for the treatment of joint and ligament instability. Additional studies with larger control and experimental groups must be conducted to evaluate the efficacy of prolotherapy for joint or ligament instability. These studies must use regimens designed to isolate treatment variables and their individual effects on both objective and subjective measurements. Given this lack of evidence, Prolotherapy is considered experimental and investigational in nature.

POSITION STATEMENT

Prolotherapy (also known as sclerotherapy) is considered experimental and investigational and is NOT a covered benefit.

CLINICAL EVIDENCE

In a randomized, controlled study, Kim, Lee, Jeong, Kim & Yoon (2010) found that intra-articular prolotherapy provided significant relief of sacroiliac joint pain, and its effects lasted longer than those of steroid injections. Further studies are needed to confirm the safety of the procedure and to validate an appropriate injection protocol.

Watson & Shay (2010) conducted a retrospective case series, studying patients from outpatient clinics in both rural and one urban center; patients were assessed, treated, and had 1 year or more follow-up. One hundred and ninety (190) patients were treated during the study period (June 1999 to May 2006); patients whose follow-up was 1 year or greater from the last treatment were included, leaving 140 patients available for data analysis. Both pain and Quality of Life scores were significantly improved at least 1 year after the last treatment. The study suggests that prolotherapy using a variety of proliferants can be an effective treatment for low back pain from presumed ligamentous dysfunction for some patients when performed by a skilled practitioner.

CODING

Non-Covered CPT® Codes

20550	Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar "fascia")
20551	Injection(s); single tendon origin/insertion
20552	Injection(s); single or multiple trigger point(s), one or two muscle(s)
20999	Unlisted procedure, musculoskeletal system, when billed for prolotherapy
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
64475	Injection, anesthetic agent and/pr steroid, paravertebral facet joint nerve; lumbar or sacral single level
64476	Injection, each additional level

Non-Covered ICD-9-CM Procedure Codes

81.92	Injection of therapeutic substance into joint or ligament
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Non-Covered HCPCS Codes

M0076	Prolotherapy
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Non-Covered ICD-9-CM Diagnosis Codes

All diagnosis codes

*Current Procedural Terminology (CPT®) ©2011 American Medical Association: Chicago, IL.

REFERENCES

Peer Reviewed

1. Hayes Directory. (2008, August 8). Prolotherapy for treatment of joint and ligamentous conditions (update search July 21, 2011). Retrieved from <http://www.hayesinc.com>

2. Kim, W.M., Lee, H.G., Jeong, C.W., Kim, C.M., & Yoon, M.H. (2010). A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. *Journal of Alternative and Complementary Medicine*, 16(12), 1285-1290.
3. Watson, J.D., & Shay, B.L. (2010). Treatment of chronic low-back pain: a 1-year or greater follow-up. *Journal of Alternative and Complementary Medicine*, 16(9), 951-958.

Government Agencies, Professional and Medical Organizations

1. Centers for Medicare and Medicaid Services. (1999, September 27). National coverage determination for prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents (150.7). Retrieved from <http://www.cms.hhs.gov/mcd/search.asp>

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• Approved by MPC.• Reformatted references. Added information from Hayes Directory update (July 2011) to original 2008 search – includes two studies conducted showing efficacy of therapy.• New template design approved by MPC.